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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,455	12/16/2003	Timothy J. Jegla	018512-001420US	9589

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/738,455	JEGLA, TIMOTHY J.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/16/2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 and 18-19, drawn to a DNA sequence comprising a nucleotide sequence encoding a potassium channel protein, a vector and host cell, classified in class 536, subclass 23.5.

II. Claims 11-15, drawn to isolated potassium channel polypeptide, classified in class 530, subclass 350.

III. Claims 16-17, drawn to an antibody that binds to potassium channel protein, classified in class 530, subclass 387.1

IV. Claims 20-26, drawn to a method for identifying a compound that increases or decreases ion flux through a voltage-gated potassium channel, classified in class 435, subclass 7.1.

V. Claims 27-29, drawn to a method of detecting the presence of potassium channel protein using antibodies, classified in class 435, subclass 7.1.

VI. Claims 27-29, drawn to a method of detecting the presence of potassium channel gene using primers and nucleic acid probes, classified in class 435, subclass 6.

VII. Claims 30-31, drawn to a method of screening for mutations of potassium channel gene using the nucleic acid sequence in the computer system, classified in class 435, subclass 6.

VIII. Claims 32-35, drawn to a method of identifying a three dimensional structure of the potassium channel protein using computer system, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

a. Inventions I-III are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are

mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Groups I-III are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. For example, the protein of Group II can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group I can be used other than to make the protein of Group II, such as a probe in nucleic acid hybridization assays. The protein of Group II can be used in materially different methods other than to make the antibody of Group III, such as in the therapeutic or diagnostic methods (e.g., in screening). Although the antibody of Group III can be used to obtain the DNA of Group I, it can be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods.

Furthermore, the distinct products require separate, distinct, and non-coextensive searches. As such, it would be burdensome to search the inventions of Groups I-III together.

b. Inventions VI and VII are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). Groups VI and VII are different methods requiring different method steps, wherein each is not required,

one for another. For example, Invention VI requires search and consideration of incubation of a biological sample capturing probe and a detection probe and determination of the presence of the DNA in the sample, which is not required by the other invention. Invention VII requires search and consideration of screening for mutation using a computer system, which is not required by the other invention. Furthermore, the distinct steps and products require separate, distinct, and non-coextensive searches. As such, it would be burdensome to search the inventions of Groups VI and VII together.

c. Inventions IV, V and VIII are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). Groups IV, V and VIII are different methods requiring different method steps, wherein each is not required, one for another. For example, Invention IV requires search and consideration of contacting a compound with the polypeptide to assess the ion flux of the polypeptide, which is not required by the other inventions.. Invention V requires search and consideration of incubation of a biological sample with antibodies specific to the channel protein, which is not required by the other inventions. Invention VIII requires search and consideration of using a computer system to generate a three dimensional structure of the polypeptide, which is not required by the other inventions. Furthermore, the distinct steps and products require separate, distinct, and non-coextensive searches. As such, it would be burdensome to search the inventions of Groups IV, V and VIII together.

d. Inventions I and (VI and VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product claimed can be used in materially different processes, such as DNA purification and gene therapy.
Additionally, searching the inventions of Groups I and (VI and VII) together would impose serious search burden. The inventions of I and (VI and VII) have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for a DNA sequence comprising a nucleotide sequence encoding a potassium channel protein and method of use are not coextensive.

e. Inventions I and (III, IV, V and VIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 802.01, MPEP § 806.06). In the instant case, the different inventions of Groups I and (III, IV, V and VIII) are unrelated product and method, wherein each is not required, one for another. For example, the isolated DNA of Invention I cannot be used together with the claimed method of Inventions IV because this invention does not recite the use or production of the DNA molecule.

f. Inventions II and (III, IV, V and VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using

that product. See MPEP § 806.05(h). In the instant case the product of invention II can be used in assays for the identification of agonist and antagonist of the polypeptide.
Additionally, searching the inventions of Groups II and (III, IV, V and VII) together would impose serious search burden. The inventions of II and (III, IV, V and VII) have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the isolated potassium channel protein and method of use are not coextensive.

g. Inventions II and (VI and VII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 802.01, MPEP § 806.06). In the instant case, the different inventions of Groups II and (VI and VII) are unrelated product and method, wherein each is not required, one for another. For example, the isolated protein of Invention II cannot be used together with the claimed method of Inventions (VI and VII) because this invention does not recite the use or production of the protein molecule.

h. Inventions VI/VII and IV/V/VIII are independent and distinct, each from other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different classification and different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

2. The claims of Groups I –IV, VII and VIII are drawn to multiple sequences (SEQ ID NO: 1, 2, 17 and 18). Each of the different sequences are independent and distinct because no common structural or functional properties are shared. Accordingly, these sequences are each subject to restriction under 35 U.S.C. § 121. Regardless of the Group elected, Applicant is additionally required to elect a single nucleic acid sequence, which if determined to be patentable, would also be patentably distinct from the other nucleic acid sequences. This requirement is made under 1192 O.G.68 Notice (November 19, 1996), as examination of more than one sequence in one application would result in an undue burden on the PTO.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

4. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS
Art unit 1647
September 16, 2006

Patent Examiner